DEPARTMENT OF HEALTH & HUMAN SERVICES 9/9/81
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

October 18, 2001

WARNING LETTER NYK 2002-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Anthony R. Dinitto, Sr., Owner
Anthony Dinitto
8163 River Road
Rome, New York 13440

Dear Mr. Dinitto:

An investigation was conducted at your dairy farm operation located at Benton Road, Marcy, New York, by U.S. Food and Drug Administration (FDA) Investigator Russ E. Davis on September 12-14 and 17, 2001. The investigation confirmed that you offered two cows for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act); and that you have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about February 21, 2001 you delivered a cow bearing your farm tag No. 209 to [redacted] where back tag No. 21ME3706 and sale tag No. 905 were additionally attached. This cow was subsequently delivered to and slaughtered at [redacted] on or about February 22, 2001. USDA analysis of tissue samples from the animal revealed the presence of the drug sulfadimethoxine at a level of 2.56 ppm in the liver and 1.86 ppm in muscle. These levels exceed the 0.1 ppm tolerance identified in 21 CFR (Code of Federal Regulations) 556.640 by more than 25 and 18 times, respectively. The presence of sulfadimethoxine at these levels in uncooked edible tissues of cattle causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about June 25, 2001, you delivered a cow bearing your farm tag No. 56 to [redacted] where you additionally attached back tag No. 21MN3686 and sale tag No. 497. This cow was subsequently delivered to and slaughtered at [redacted] on or about June 26, 2001. USDA analysis of tissue samples from the animal revealed the presence of the drug penicillin at a level of 0.17 ppm in kidney tissue. This level exceeds the 0.05 ppm tolerance identified in 21 CFR 556.510. The presence of penicillin at this level in kidney tissue causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act. Our investigator also found you failed to follow label directions with respect to the administration of cephapirin sodium in excess of the recommended treatment regimen to this cow.

Our investigation found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

Our investigation also revealed you adulterated the drugs sulfadimethoxine, penicillin G procaine, and cephapirin sodium within the meaning of Section 501(a)(5) of the Act when you used the drugs in an extralabel manner without veterinary supervision. Your use of drugs in dairy cows at higher than labeled dosages causes the drugs to be unsafe to use.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action - without further notice. This may include seizure and/or injunction.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. As a dairy farmer, you are the individual who introduces or offers for introduction into interstate commerce the adulterated animal. It is not necessary for you to personally ship an animal into interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to an auction barn and/or slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken, or intend to take, to prevent a recurrence of these or similar violations. Your response should be directed to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York 14202, telephone 716-551-4461, ext. 3168.

Sincerely,

Jerome G. Woysnner
District Director